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CALIFORNIA STEM CELL
TREATMENT CENTER, INC.,
CELL SURGICAL NETWORK
CORPORATION, ELLIOT B. LANDER, M.D.
and MARK BERMAN, M.D.

**UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA
EASTERN DIVISION**

UNITED STATES OF AMERICA,

Plaintiff,

v.

CALIFORNIA STEM CELL
TREATMENT CENTER, INC., a
California corporation, CELL SURGICAL
NETWORK CORPORATION, a
California corporation, and ELLIOT B.
LANDER, M.D., MARK BERMAN,
M.D., individuals,

Defendants.

CASE NO. 5:18-CV-01005-JGB-KK

Hon. Jesus G. Bernal
Riverside, Courtroom 1

**OBJECTIONS TO
GOVERNMENT'S [PROPOSED]
FINDINGS OF FACT AND LAW
(LOCAL RULE 52-7)**

Action Filed: May 9, 2018
Trial Date: May 4, 2021
Closing Agmt.: July 9, 2021

I. INTRODUCTION

Defendants California Stem Cell Treatment Center, Inc., Cell Surgical Network Corporation, Elliot Lander, M.D., and Mark Berman, M.D. (collectively, “Defendants”), hereby object to the Government’s Proposed Findings of Fact and Conclusions of Law pursuant to United States District Court for the Central District of California Local Rule 52-7 and this Court’s orders at trial. Specifically, the Government improperly changes stipulated facts and fails to support proposed findings of fact with appropriate citation to the record. Pursuant to Local Rule 52-7, Defendants object to certain findings of fact and request that the Court strike such proposed findings of fact and disregard when determining the conclusions of law.

II. ARGUMENT

A. Government Wrongly Changes Stipulated Facts

The Government changed the terms of stipulations; thereby, creating new facts that were not stipulated to and do not otherwise exist in evidence. In the proposed final pretrial order, the parties submitted stipulated facts and explicitly explained the use of the neutral term “Treatments.” Proposed Final Pretrial Conf. Or., ECF No. 113-1. However, the Government modified the stipulated facts to change the term “Treatments” to “product.” Gov’t Proposed Findings at 1 n.1, ECF No. 169-1. These are no longer stipulated facts. Therefore, there is no citation to evidence for numerous proposed facts.

This is not a simple change of words. The term was not chosen merely for “simplicity.” *See* Gov’t Proposed Findings at 1 n.1, ECF No. 169-1. The crux of the litigation is whether Defendants’ treatments are surgical procedures or products—the Court used the neutral term “treatments” in its order denying the Government’s motion for summary judgment and ordered both sides to use “treatments” at trial. Accordingly, Defendants stipulated to facts using the neutral term “treatments.” Defendants have never stipulated to the use of the term

1 “products.” To the extent the Government relies on the purported “stipulated
2 facts” in the conclusions of law, the Court should find that these are not supported
3 by the record and not consider the facts when making its determination of law.

4 The proposed facts at issue are:

- 5 • No. 10: “Once approved for inclusion in the CSN network, CSN
6 affiliates purchase supplies from CSN to make the SVF products.”
- 7 • No. 23: “CSN affiliate doctors have administered SVF products to
8 over 6,000 patients.”
- 9 • No. 37: “Defendants use a collagenase product made in Indiana to
10 prepare their SVF product.”
- 11 • No. 60: “Defendants’ processing of adipose tissue to manufacture the
12 CSCTC products involves removing adipocytes from the adipose
13 tissue.”
- 14 • No. 177: “There are not now, nor have their ever been, any approved
15 new drug applications (“NDAs”) filed with the FDA pursuant to 21
16 U.S.C. § 355(b) or (j) for the CSCTC products.”
- 17 • No. 178: “There are not now, nor have their ever been, any approved
18 biologics license applications (“BLAs”) filed with the FDA pursuant
19 to 42 U.S.C. § 262 for the CSCTC products.”
- 20 • No. 179: “None of the CSCTC products have been licensed or
21 approved by FDA for any use.”
- 22 • No. 187: “Although Defendants have had discussions with FDA
23 concerning their desire to study the SVF/Vaccinia product pursuant to
24 an IND under 21 U.S.C. § 355(i), no IND is currently in effect for that
25 product or any of Defendants’ other CSCTC products.”

26 **B. The Government Fails To Cite Factual Support**

27 This Court instructed the parties to cite to the factual record for each
28 proposed finding of fact. (5/13/21 PM Tr. 55:8-19). The Government fails to

adequately support numerous proposed facts and in many cases cite to transcript excerpts that are irrelevant or stand for the opposite. Consistent with the Government's continual overreach and attempts to eliminate 21 C.F.R. § 1271.15, the Same Surgical Procedure Exception, from the Code of Federal Regulations, the Government attempts to force the record to fit into their theory of the case. Many of their factual assertions are simply unsupported.¹ For example:

- No. 41: The Government cites an entirely irrelevant case for the factual proposition that “safety concerns reasonably arise when an enzyme is used to disrupt and digest adipose tissue.” There is no citation to evidence. The cited case does not analyze Defendants’ enzyme, Liberase; nor does it analyze Defendants’ SVF Surgical Procedure, Expanded MSC Surgical Procedure, SVF/ACAM2000 Surgical Procedure.
- No. 42: The Government cites to a few of Defendants’ protocols for the proposition that the protocols do not require “Defendants to confirm that the collagenase-containing enzyme used during production has been eliminated” but each of the cited exhibits state the opposite: the three washing stages are done to eliminate the collagenase (Liberase).
- No. 70: The cited transcripts and exhibits do not support the Government’s proposed fact that the Liberase changes the main attributes of cells or their behavior, indeed, Dr. Reid stated the opposite and the surgical manuals make no statements about the attributes of the cells.
- No. 82: The Government cites essentially the entirety of Defendants’ trial testimony for the proposed fact that Defendants did not proffer

¹ In certain proposed findings, the Government cites Defendants’ opening statement, which is not a fact in evidence. *See* Proposed Fact No. 204.

“results of any [] testing for the CSCTC products to meet Defendants’ burden of showing the SVF cells have not changed.” This is both improper and unsupported as Defendants provided explicit testimony and evidence that the SVF Cells did not change.

- Nos. 119 and 120: There are no citations to the record to support the proposed facts that the surgical procedures are governed by the Public Health Safety Act. Instead the Government solely cites to 21 C.F.R. §§ 1271.3 and 1271.15.

III. CONCLUSION

Accordingly, Defendants request that the Court strike the proposed findings of fact that are not supported by the record and disregard such proposed findings when determining the conclusions of law.

Dated: June 15, 2021

JONES DAY

By: /s/ Celeste M. Brecht
Celeste M. Brecht

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